REMARKS

Formal Matters

Applicant has amended claims 4-10, 12, and 13. Applicant has also canceled claims 1-3 and 11.

Claims 4-10 and 12-14 are currently pending.

Claim Objection

The Office objected to claims 1 and 4 for reciting "[a]n antibody." *See* Office Action at ¶ 4. As noted above, Applicant has canceled claim 1, without prejudice or disclaimer. Applicant has amended claim 4 to read "[a]n isolated antibody." Therefore, Applicant requests that this objection to claim 4 be withdrawn.

Enablement Rejections

Claims 8 and 9 were rejected by the Office because the specification allegedly does not reasonably provide enablement to make or use the present invention. *See* Office Action at ¶ 6. Specifically, claims 8 and 9 were rejected by the Office under 35 U.S.C. § 112 because it is allegedly not clear from the disclosure that the deposit of the cell cultures which produce monoclonal antibodies of the invention, meets all the criteria set forth in 37 C.F.R. § 1.801-1.809. *Id.* In response, Applicant files the attached Microorganism Deposit Declaration under 37 C.F.R. § 1.808(a). Applicant notes that the specification discloses the date of deposit and name and address of the depository at the paragraph spanning pages 3-4. Thus, Applicant submits that the rejection of claims 8 and 9 have been obviated and request that the rejection be withdrawn.

The Office also rejected claims 1-7 and 10-14, because allegedly "it would take an undue amount of experimentation for one skilled in the art to practice the claimed

invention." Office Action at ¶ 7. Applicant respectfully traverses. Although Applicant believes that these concepts are supported by the specification, Applicant has canceled claims 1-3 and 11, as noted above, and therefore, the rejection as to these claims is moot. Applicant reserves the right to pursue the canceled subject matter in a separate application.

One of skill in the art would be able to make and use the claimed invention, as amended, using the following teachings in the application as a guide:

- A description of antibodies, fragments, and their binding characteristics is provided on page 3, line 20 to page 4, line 30 of the specification. A specific example of two monoclonal antibodies is also provided along with information regarding its deposit under Accession Nos. DSM ACC2540 and DSM ACC2541.
- Examples 1 and 2 demonstrate the preparation and isolation of transferrin from human sera, while Example 3 teaches how unglycosylated transferrin is prepared via recombinant methods or enzymatic deglycosylation.
- The specification at page 4, line 32 to page 6, line 29 and Example 5 teach how to make an antibody of the invention, e.g., immunization and how a monoclonal antibody-producing hybridoma can be prepared.
- The determination of antibody specificity is described in Example 5 at page 10, line 19 to page 11, line 20.
- Expression, production, isolation, and purification of the antibodies are detailed in Example 5 at page 11, line 22 to page 12, line 35.
- Examples 6 and 7 describe how to determine the specificity of antibodies for solid phase antigens and antigens in solution.

- Example 8 describes binding of the antibodies of the invention to specific regions of the CDT sequence.

One of ordinary skill in the art based on these teachings would be able to both make and use the antibodies of the invention. In light of these arguments, Applicant requests that the Office withdraw the enablement rejection of claims 4-7, 10, and 12-14.

Written Description Rejection

Claims 1-7 and 10-14 have been rejected by the Office under 35 U.S.C. § 112, first paragraph, as allegedly "containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention." Office Action at ¶ 8. Applicant respectfully traverses.

As discussed above, Applicant has canceled claim 1-3 and 11, without prejudice or disclaimer. Applicant was clearly in possession of the subject matter of claims 4-7, 10, and 12-14 at the time of filing. The Office is improperly attempting to limit the scope of the claims based on an actual reduction to practice disclosed in the specification. The Office's position is inconsistent with the Office's own Synopsis of Application of

Written Description Guidelines, which indicates that written description can be met by

> [s]how[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

Guidelines, 66 Fed. Reg. at 1106 (emphasis added). In *Noelle v. Lederman*, 355 F.3d at 1349, the court, basing its reasoning on past precedent, stated that "as long as an applicant has disclosed a 'fully characterized antigen,' either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that described antigen."

Applicant respectfully submits that the sequences to which the antibodies of the invention bind are disclosed in the specification at, for instance, claim 4 itself. Furthermore, the specification demonstrates that antibodies that bind to these sequences surprisingly have the ability to bind CDT in an aqueous solution. Based on the Office's own guidelines and the holdings of the courts, Applicant asserts that the claims fulfill the written description requirement and request that the Office withdraw this rejection.

Indefiniteness Rejections

The Office rejected claims 2-6 under 35 U.S.C. § 112, second paragraph, a being indefinite. *See* Office Action at ¶ 10. Specifically, the Office rejected claim 2 for reciting "insubstantially," claim 3 for reciting "binding behavior," and both claims for reciting "peptides P1 and P2." *Id.* Applicant notes that claims 2 and 3 have been canceled, without prejudice or disclaimer, rendering these rejections moot.

The Office specifically rejected claim 4 for reciting the abbreviation "CDT." Applicant has replaced "CDT" with "carbohydrate deficient transferrin" in claim 4, as well as claims 12 and 13. Therefore, Applicant requests that the Office withdraw the indefiniteness rejection of claim 4.

The Office specifically rejected claims 5 and 6 because allegedly it is "not clear which 'region' in the segments (1) to (4) to which the antibody binds is part of the claimed invention." *Id.* Applicant respectfully submits that the "regions" recited in claims 5 and 6 are clear to one of ordinary skill in the art when read in light of the specification and, particularly, independent claim 4, from which the claims depend. The "regions" that claims 5 and 6 refer to are the four sequences listed in claim 4. It is clear to one of ordinary skill in the art that claims 5 and 6 refer to "regions" of the carbohydrate deficient transferrin sequence to which the isolated antibody may bind. Nevertheless, Applicant has amended claims 5 and 6 to distinctly point out that the "regions" are those of carbohydrate deficient transferrin, and the isolated antibody binds to three of the four regions. Based upon these arguments and amendment, Applicant respectfully requests that the Office withdraw the indefiniteness rejection of claims 5 and 6.

Anticipation Rejections

The Office rejected claims 1-3, 7, 10, 11, 13, and 14 under 35 U.S.C. § 102(b), as being anticipated by EP 0605 627, WO 93/06133, and U.S. Patent No. 5,702,904, all of which originate from the same family. The Office also rejected claims 1, 7, 10, 13, and 14 under 35 102 (b), as being anticipated by WO 00/36418. *See* Office Action at ¶¶ 11-15. In addition, the Office stated that "[c]laims 4, 8-9, and 12 are free of prior art." Office Action at ¶ 16. Applicant assumes that the Office also meant to include claims 5 and 6, which depend from claim 4, as being free of prior art.

Applicant respectfully traverses the rejections of the claims. However, Applicant has canceled claims 1-3 and 11 without prejudice or disclaimer. Further, Applicant has

amended claims 7, 10, and 13, so that they depend from claim 4, which is free of the prior art. Because of these amendments, claim 14, which depends upon claim 13, indirectly depends from claim 4, which is free of the prior art. Based on these amendments, Applicant respectfully requests that the Office withdraw the four anticipation rejections of claims 7, 10, 13, and 14.

Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: April 14, 2006

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